**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**INSTRUMENT ONLY TEMPLATE**

**A. 510(k) Number:** K060656

**B. Purpose for Submission**: Traditional 510(k)

**C. Manufacturer and Instrument Name**: Sysmex America, Inc. Sysmex® XS Automated Hematology Analyzer series (XS-100i and XS-800i).

**D. Type of Test or Tests Performed**: 21 Complete Blood Count analysis parameters in whole blood.

**E. System Descriptions:**

1. Device Description: The XS is an automated hematology analyzer which consists of three principal units: (1) Main unit which aspirates, dilutes, mixes and analyzes whold blood samples; (2) Auto Loader on the XS-1000i that supplies samples to the Main Unit automatically ; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system. The XS-1000i and XS-800i are the same instruments except that the XS-1000i has the ability to install an auto loader and the XS-800i uses a manual mode only.

2. Principles of Operation: The XS performs hematology analyses using the following methods: Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method. Blood cells pass through the aperture of the detector surrounded by a sheath fluid using the sheath flow method. The principle of flow cytometry is also used. A semiconductor laser beam is emitted to the blood cells passing through the flow cell. The forward scattered light is received by the photodiode, and the lateral scattered light and lateral fluorescent light are received by the photo multiplier tube. This light is converted into electrical pulses, thus making it possible to obtain blood cell information. Hemoglobin is measured with the SLS-hemoglobin method using Sodium Lauryl Sulfate, which is an analysis method used in previous Sysmex instrumentation.

3. Modes of Operation: Sampler Mode, Capillary Mode, and Manual Mode with XS-1000i and Manual Mode and Capillary Mode with XS-800i.

4. Specimen Identification: Barcode only with XS-1000i when Sampler is connected.

5. Specimen Sampling and Handling: Sampler Mode, Capillary Mode, and Manual Mode with XS-1000i and Manual Mode and Capillary Mode with XS-800i.

6. Calibration: Automatic and manual calibration using fresh normal blood.

7. Quality Control: Commercial control blood is used and analyzed using X-bar control and L-J (Levy-Jennings) Control programs.

8. Software: Comprehensive software documentation at a Moderate Level of Concern was provided by Sysmex.

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes__X____ or No_____

**F. Regulatory Information**:

1. Regulation section: 21 CFR 864.5220. Automated differential cell counter

2. Classification: Class II

3 Product code: GKZ

4. Panel: Hematology (81)

**G. Intended Use:**

1. Indication(s) for Use: The Sysmex XS is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories.

2. Special Conditions for Use Statement(s): N/A

**H. Substantial Equivalence Information**

1. Predicate Device Name(s) and 510(k) numbers:

   Sysmex XT-Series: K021241, Sysmex XE-2100: K992875

2. Comparison with Predicate Device:

| **Similarities** | | |
|---|---|---|
| Item | Device | Predicate |
| Intended Use | Automated blood cell analyzer. | XT-Series and XE-2100: Same. |
| Sample Type | Whole Blood | XT-Series and XE-2100: Same |

| Similarities | | |
|---|---|---|
| Item | Device | Predicate |
| Bar Code | Yes | XT-Series and XE-2100: Same |

| Differences | | |
|---|---|---|
| Item | Device | Predicate |
| Sample Volume | 20µL, Auto loader mode<br>20µL, Manual mode<br>20µL, Capillary dilution | XT-Series: 150µL, Cap piercer mode<br>85µL, Manual mode<br>40µL, Capillary dilution<br>XE-2100: 200µL, Cap piercer mode<br>130µL, Manual mode<br>40µL, Capillary dilution |
| Parameters | WBC, Neut%/#, Lymph%/#, Mono%/#, Eos%/#, Baso%/#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV | XT-Series: Same plus: RET%/#, IRF<br><br>XE-2100: Same plus: NRBC%/#, RET%/#, IRF |
| Principles | RBC, PLT: DC detection method,<br>WBC: Fluorescent Flow Cytometry-WBC Diff channel using semiconductor laser,<br>HGB: SLS-Hgb method. | XT-Series:<br>RBC, PLT: DC detection method,<br>WBC: Flow Cytometry method using semiconductor laser detection method,<br>HGB: SLS-Hgb method<br>XE-2100:<br>RBC, PLT: Sheath-flow DC detection method,<br>WBC: Flow Cytometry method using semiconductor laser detection method,<br>HGB: SLS-Hgb method. |
| QC System | L-J: 20 files with 180 points per file. | XT-Series: L-J: 20 files with 300 points per file.<br>XE-2100: L-J: 10 files with 300 points per file. |

| Differences | | |
|---|---|---|
| Item | Device | Predicate |
| # of tests/hour | Approx. 60 | XT-Series: Approx 80<br>XE-2100: Approx 113-150 |

**I. Special Control/Guidance Document Referenced (if applicable):** *Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells: final Guidance for Industry and FDA*, issued on December 4, 2001.

**J. Performance Characteristics*:***

1. Analytical Performance:

*a. Accuracy*: **Table 1: XS vs. XT**

| **Parameters** | **Correlation (r)** | **Regression ($r^2$)** | **Regression Equation** | **Number of Samples** |
|---|---|---|---|---|
| WBC | 1.00 | 0.9979 | y=0.9438x+0.754 | 609 |
| RBC | 1.00 | 0.9951 | y=1.0049x-0.0492 | 609 |
| HGB | 1.00 | 0.9966 | y=1.0119x0.2155 | 609 |
| HCT | 1.00 | 0.9941 | y=1.0163x-0.7441 | 609 |
| MCV | 0.99 | 0.9887 | y=1.000x+0.2805 | 609 |
| MCH | 0.99 | 0.9772 | y=0.9882+0.3751 | 609 |
| MCHC | 0.95 | 0.8951 | y=0.9459+1.6856 | 609 |
| PLT | 1.00 | 0.9948 | y=0.9885x-4.6694 | 609 |
| RDW-SD | 0.99 | 0.9784 | y=0.9767x+0.8594 | 607 |
| RDW-CV | 0.99 | 0.9891 | y=1.0111x-0.2426 | 607 |
| MPV | 0.82 | 0.6774 | y=0.9247x+0.9571 | 574 |
| Neut% | 1.00 | 0.9966 | y=1.0219x+0.0023 | 579 |
| Lymph% | 1.00 | 0.9992 | y=0.9694x-0.064 | 581 |
| Mono% | 0.98 | 0.9702 | y=0.9792x+0.0584 | 579 |
| Eos% | 0.98 | 0.9668 | y=1.0474x-0.0036 | 595 |
| Baso% | 0.45* | 0.2032 | y=0.3312x+0.0261 | 594 |

*The lower r-value on the basophile% parameter is typically lower than the other parameters due to the low frequency of the basophile cell type.

*b.Precision/Reproducibility*:

**Table 2: Within Run Precision using blood samples (CLSI EP5)**

| N=20 Samples | WBC | RBC | HGB | HCT | MCV | MCH | MCHC | PLT |
|---|---|---|---|---|---|---|---|---|
| **#1 Mean** | 8.73 | 3.93 | 12.2 | 37.0 | 94.2 | 31.1 | 33.0 | 208.1 |
| **SD** | 0.14 | 0.03 | 0.1 | 0.4 | 1.0 | 0.2 | 0.4 | 3.8 |
| **CV%** | **1.65** | **0.72** | **0.6** | **1.0** | **1.0** | **0.6** | **1.3** | **1.8** |
| | | | | | | | | |
| **#2 Mean** | 7.45 | 4.89 | 14.8 | 44.5 | 91.2 | 30.3 | 33.2 | 223.3 |
| **SD** | 0.13 | 0.03 | 0.1 | 0.4 | 1.1 | 0.1 | 0.4 | 4.1 |
| **CV%** | **1.74** | **0.58** | **0.5** | **0.8** | **1.2** | **0.5** | **1.3** | **1.8** |
| | | | | | | | | |
| **#3 Mean** | 8.22 | 4.81 | 13.4 | 41.1 | 85.8 | 27.9 | 32.6 | 145.9 |
| **SD** | 0.11 | 0.02 | 0.0 | 0.4 | 0.8 | 0.1 | 0.4 | 4.3 |
| **CV%** | **1.36** | **0.38** | **0.4** | **0.9** | **0.9** | **0.5** | **1.1** | **2.9** |
| | | | | | | | | |
| **#4 Mean** | 7.45 | 4.50 | 13.1 | 40.7 | 90.5 | 29.0 | 32.1 | 226.3 |
| **SD** | 0.12 | 0.03 | 0.1 | 0.4 | 1.1 | 0.2 | 0.5 | 3.1 |
| **CV%** | **1.55** | **0.73** | **0.5** | **1.0** | **1.2** | **0.7** | **1.4** | **1.4** |
| | | | | | | | | |
| **#5 Mean** | 6.58 | 3.94 | 13.2 | 39.0 | 99.0 | 33.4 | 33.8 | 382.4 |
| **SD** | 0.13 | 0.05 | 0.1 | 0.5 | 0.9 | 0.4 | 0.4 | 6.1 |
| **CV%** | **2.03** | **1.22** | **0.4** | **1.3** | **0.9** | **1.1** | **1.3** | **1.6** |
| **Avg CV%** | **1.67** | **0.73** | **0.5** | **1.0** | **1.0** | **0.7** | **1.3** | **1.9** |

c. *Linearity*: Linearity was evaluated using a series of dilutions of residual patient material. Replicates were measured at each level and represented the range of linearity.

**Table 3 Linearity**

| Parameter | Range Tested | Units | $r^2$ | r | Slope | Intercept |
|---|---|---|---|---|---|---|
| **WBC** | 0-1.110 | $x10^3/\mu L$ | 0.9975 | 1.00 | 1.0195 | 0.0034 |
| | 0.080-172.40 | $x10^3/\mu L$ | 0.9993 | 1.00 | 1.0103 | 0.3659 |
| | 0.015-448.63 | $x10^3/\mu L$ | 0.9997 | 1.00 | 0.9963 | 1.0965 |
| | | | | | | |
| **RBC** | 0—8.93 | $x10^6/\mu L$ | 0.999 | 1.00 | 1.0096 | 0.0393 |
| | | | | | | |
| **HGB** | 0—26.4 | g/dL | 0.9992 | 1.00 | 1.0132 | 0.0009 |
| | | | | | | |
| **HCT** | 0—74.9 | % | 0.9959 | 1.00 | 1.0999 | 0.7802 |
| | 0.4—64.9 | % | 0.9919 | 1.00 | 1.0103 | 1.7469 |
| | | | | | | |
| **PLT** | 0—117 | $x10^3/\mu L$ | 0.9997 | 1.00 | 0.9949 | 1.3913 |
| | 3--5670 | $x10^3/\mu L$ | 0.9981 | 1.00 | 0.9876 | -41.069 |

d. *Carryover*:

Carryover was evaluated by assaying a sample with high concentration three consecutive times followed immediately by testing a low sample consecutively 3 times. This is the method in *Guidelines for the valuation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications*. ISLH, January 14, 1994.

**Table 4: Carryover**

| Parameter | % Carryover | % Carryover | Manufacturer Specifications |
|---|---|---|---|
| **WBC** | 0.01 | -0.02 | ≤1% |
| **RBC** | 0.00 | -0.21 | ≤1% |
| **HGB** | 0.00 | 0.59 | ≤1% |
| **HCT** | 0.00 | 0.00 | ≤1% |
| **PLT** | 0.05 | 0.00 | ≤1% |

*e. Interfering Substances*:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

Reference Values: Normal specimens from this study fell within these ranges.

**Table 5: XS Reference Range Verification**

| Parameter | Females<br><br>n=133 | Males<br><br>n=182 | Units |
|---|---|---|---|
| **WBC** | 3.98-10.04 | 4.23-9.07 | $x10^3/\mu L$ |
| **Neut%** | 34.0-71.1 | 34.0-67.9 | % |
| **Lymph%** | 19.3-51.7 | 21.8-53.1 | % |
| **Mono%** | 4.7-12.5 | 5.3-12.2 | % |
| **Eo%** | 0.7-5.8 | 0.8-7.0 | % |
| **Baso%** | 0.1-1.2 | 0.2-1.2 | % |
| **Neut#** | 1.56-6.13 | 1.78-5.38 | $x10^3/\mu L$ |
| **Lymph#** | 1.18-3.74 | 1.32-3.57 | $x10^3/\mu L$ |
| **Mono#** | 0.24-0.36 | 0.30-0.82 | $x10^3/\mu L$ |
| **Eo#** | 0.04-0.36 | 0.04-0.54 | $x10^3/\mu L$ |
| **Baso#** | 0.01-0.08 | 0.01-0.08 | $x10^3/\mu L$ |
| **RBC** | 3.93-5.22 | 4.63-6.08 | $x10^6/\mu L$ |
| **HGB** | 11.2-15.7 | 13.7-17.5 | g/dL |
| **HCT** | 34.1-44.9 | 40.1-51.0 | % |
| **MCV** | 79.4-94.8 | 79.0-92.2 | fL |
| **MCH** | 25.6-32.2 | 25.7-32.2 | pg |
| **MCHC** | 32.2-35.5 | 32.3-36.5 | g/dL |
| **RDW-CV** | 11.7-14.4 | 11.6-14.4 | % |
| **RDW-SD** | 36.4-46.3 | 35.1-43.9 | fL |
| **PLT** | 182-369 | 163-337 | $x10^3/\mu L$ |

## K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

## L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.